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Review

Who is the right patient for TAVI?

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ABSTRACT

Transcatheter aortic valve implantation (TAVI) has rapidly emerged as a valid therapeutic option for patients with severe symptomatic aortic stenosis who are high risk or ineligible for conventional surgical aortic valve replacement. Despite its minimally invasive nature, TAVI is invariably associated with complications in these old patients that may affect outcomes. Although the success of TAVI is determined by multiple factors, good screening and appropriate patient selection is crucial. Selection of the right patient includes the determination of risk levels and feasibility of a safe procedure in each individual case. Here, we describe below our critical appraisal of patient selection for TAVI.

Contents

Introduction

Transcatheter aortic valve implantation (TAVI) is now an established treatment option for patients with severe symptomatic aortic stenosis who are considered too high risk or ineligible for surgical aortic valve replacement [1–3]. The Edwards SAPIEN transcatheter heart valve (THV; Edwards, Irvine, CA, USA) and Medtronic CoreValve (Medtronic, Minneapolis, MN, USA) are available for commercial use in Europe and more than 80,000 patients have already undergone TAVI. Despite its minimally invasive nature, TAVI is invariably associated with complications that may affect outcomes. Appropriate patient selection includes the determination of risk levels and the assessment of the feasibility and safety of the procedure for each individual patient. It is crucial that selection of eligible patients be carried out by a team of experienced interventional cardiologists, cardiac surgeons, anesthetists, and imaging specialists, defined as the "Heart Team."

Risk evaluation

TAVI is indicated for selected patients at high or prohibitive surgical risk. Surgical risk has been quantified using the logistic European System for Cardiac Operative Risk Evaluation (Logistic EuroScore) and the Society of Thoracic Surgeons (STS) Predicted Risk Mortality score. However, a number of comorbid conditions associated with adverse surgical outcomes are not included in these risk calculation scores, including disabling arthritis, liver cirrhosis, porcelain aorta, chest radiation, dementia, recurrent pulmonary emboli, right ventricular failure, cancer, cachexia, and frailty. Frailty has been recently recognized as a significant factor to be taken into account when selecting patients for TAVI. Indeed, frailty is

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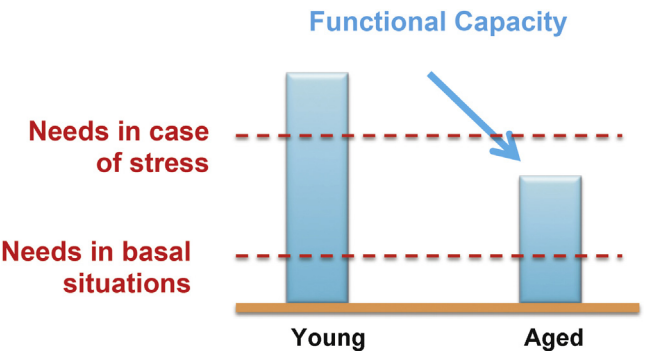

Fig. 1. Frailty is associated with diminution of physical reserve which increases vulnerability to stress.

considered to be a distinct clinical syndrome characterized by a decrease in muscle mass and energy expenditure as well as malnutrition, leading to extreme vulnerability to adverse events. In addition, the diminution of physical reserve associated with frailty increases vulnerability to stress (Fig. 1) [4]. Although accurate assessment of frailty is difficult to perform routinely, evaluation of frailty by geriatricians could be useful for patient selection. Moreover, when there is doubt about the outcome after TAVI, balloon aortic dilatation could prove to be a very good initial test before planning TAVI within 4 weeks after reassessment of the patient. The European system for cardiac operative risk evaluation score II (ESII) was recently developed to improve the accuracy of the logistic Euroscore. The ES II integrates partial quantification of frailty into the model [5]. There are two studies showing that ES II has better predictive performance compared to logistic Euroscore and STS, especially in transfemoral (TF) cohorts [6,7]. However, even this model cannot adequately predict 30-day and 1-year mortality after TAVI. Additional studies are needed to create a new TAVI score to further improve the identification of the patients who would benefit from TAVI.

Renal function is reported to be associated with poor outcomes after TAVI. A recent report showed that chronic kidney disease stage 4 before TAVI is associated with an increased risk of 30-day and 1-year mortality [8]. It has been observed that not only pre-procedural renal function but also post-procedural renal function after TAVI have an impact on the outcome. The results of other recently published analyses have demonstrated that acute kidney injury (AKI), which is defined as a post procedural decrease in renal function, is also associated with early and late mortality [9]. In order to prevent the occurrence of AKI, TAVI patients should receive optimal hydration, the total amount of contrast media should be minimized and the TF approach should be avoided in patients with aortic debris in order to avoid distal embolization. The presence of aortic debris can be easily assessed by transesophagal echocardiography (TEE) or computed tomography scan and should be part of the screening.

Coronary artery disease

Coronary artery disease (CAD) is a frequent comorbidity in patients undergoing TAVI [10] and coronary angiogram is also part of the screening process. We think that it should be performed via the radial route in order to avoid utilizing the femoral arteries before TAVI. Whether coronary revascularization should be performed in TAVI candidates is still under debate as no randomized studies have yet addressed this subject. However, coronary revascularization by means of percutaneous coronary intervention seems reasonable in patients with significant CAD, particularly in the presence of proximal severe stenosis in major coronary arteries [11]. Several issues, including completeness and timing of revascularization in TAVI patients with CAD, remain open and further studies are needed to clarify the management of CAD in TAVI candidates.

Vascular access screening

Selection of the vascular access site is a very important step requiring careful pre-procedural screening. All patients are initially evaluated for transfemoral approach feasibility. Vascular assessment is most commonly performed using selective iliac angiography (Fig. 2) and multidetector computed tomography (MDCT) (Fig. 3). The peripheral vasculature necessitates precise assessment including the minimal vessel size, tortuosity, and calcification of the ilio-femoral arteries. The presence of aortic debris, mobile plaques, excessive calcifications, or extreme tortuosity of the descending thoracic aorta should also be carefully assessed. In such cases, it is important to discuss and assess alternative approaches such as the trans-subclavian, trans-aortic, or transapical routes.

Evaluation of the femoral access using selective contrast angiography can be done during coronary angiogram. An SFAR ratio >1.05 (outer Sheath diameter to Femoral Artery minimal luminal diameter Ratio) has been identified as a predictor of major vascular complications and 30-day mortality, as defined by the Valve Academic Research Consortium (VARC) [12]. MDCT is also recommended for screening of the peripheral vasculature in potential TAVI recipients [13], but we should be careful to avoid accumulation of contrast media in these patients with poor renal function.

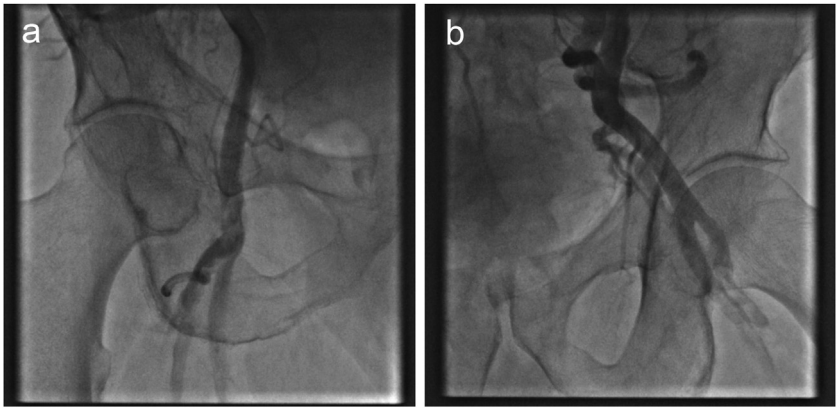

Fig. 2. Vascular assessment using contrast angiography including the size, tortuosity, and calcification of the ilio-femoral arteries: (a) right ilio-femoral artery and (b) left ilio-femoral artery.

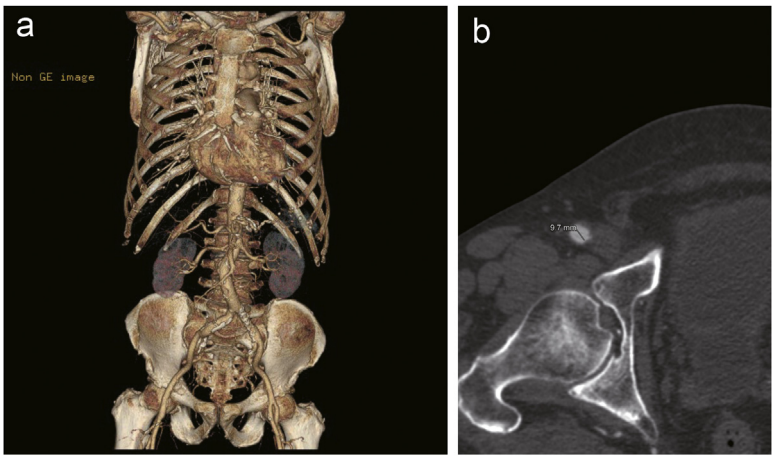

Fig. 3. (a) and (b) Vascular assessment using multidetector computed tomography including the size, tortuosity, and calcification of the ilio-femoral arteries.

Annulus assessment

Accurate measurement of the aortic annulus diameter is crucial for appropriate valve sizing and for the outcomes of the procedure. The aortic annulus is a complex 3-dimensional structure, and the virtual ring has an oval shape formed by the junction of the nadirs of all aortic valve leaflets at the distal part of the left ventricular outflow tract [14]. Overestimation of valve size can cause catastrophic annulus rupture, while underestimation may result in valve migration or post-procedural paraprosthetic aortic regurgitation (AR). AR has been recognized as an independent predictor of long-term mortality [15]. The two-year follow-up results of the PARTNER US trial revealed that not only >3/4 AR, but also grade 2 AR had a significant impact on mortality [16]. Transthoracic echocardiography (TTE), and better TEE were used until recently to assess the annulus dimensions, but today MSCT is recognized as the gold standard technique of annulus size assessment. Many studies have shown that CT-guided valve sizing significantly reduces the incidence of post-procedural AR compared to TEE [17]. Aortic annulus assessment is easy to perform using MSCT because it is a 3-D acquisition with high spatial resolution in the 3 axes providing good evaluation of the annulus and valve calcifications. Simple rules should be followed: measurements should be performed in systole at the hinge point attachment of the three aortic cusps, perpendicular to the aortic root axis. In this plane, this virtual ring is usually oval in shape with a long lateral axis and short antero-posterior axis. The antero-posterior axis is the axis measured by 2D echo. The annulus surface can be traced manually and measured using the geometric mean annulus diameter as mDiam-CT = $2\sqrt{}$(annulus surface area/π) (Fig. 4). The mean annulus diameter is in fact the mean value of all diameters whatever the shape of the annulus. 3D TEE improves the accuracy of annulus sizing but remains to date less accurate than MSCT assessment.

Bioprosthesis type, size, and positioning

Two THV systems are currently available for implantation in Europe. The Edwards SAPIEN XT THV is a balloon-expandable valve that consists of a radiopaque cobalt chromium frame, trileaflet bovine pericardial leaflets, and polyethylene terephthalate fabric skirt. The Edwards SAPIEN XT THV can be implanted in native annuli with diameters of 16 to 27 mm (20, 23, 26, and 29 mm valve). The optimal ratio between valve diameter and mean annulus diameter as assessed by MSCT is 1.055. The Medtronic CoreValve bioprosthesis is a self-expandable valve manufactured from a radiopaque nitinol support frame, trileaflet porcine pericardial leaflets, and porcine pericardium fabric skirt. The CoreValve can be implanted in native annuli with diameters ranging from 17 to 29 mm (26, 29, and 32 mm valve). Because of the self-deployment nature of the CoreValve, selection of the CoreValve diameter should be based on the maximal annulus diameter rather than the mean diameter as assessed by MSCT and the ratio should be >1.

Optimal positioning of the valve is crucial to avoid valve embolization and coronary occlusion. In addition it also reduces the risk of para-valvular leak. The optimal landing zone and skirt height for Edwards valve is summarized in Fig. 5 [18]. In CoreValve recipients, if the aortic annulus plane is 12 mm higher than the lower end of the metal frame, the gap between the annulus plane and the skirt may cause a severe paravalvular leak.

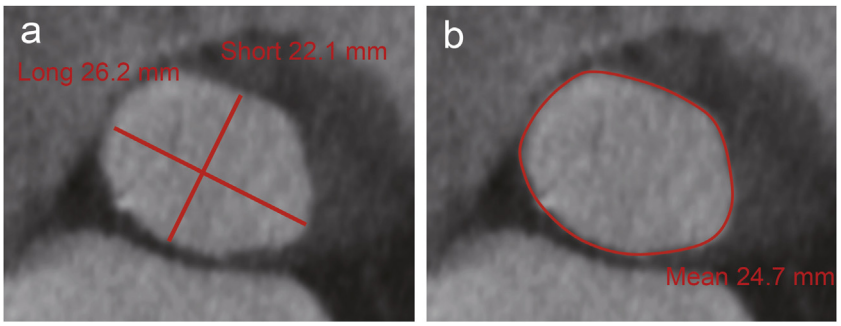

Fig. 4. Measurement of an aortic annulus on multidetector computed tomography: (a) the short-axis and long-axis diameter were measured as mm and mm, respectively and (b) mean-diameter was calculated as mm based on the formula: mean Diam-CT = $2\sqrt{}$(annulus surface area/π).

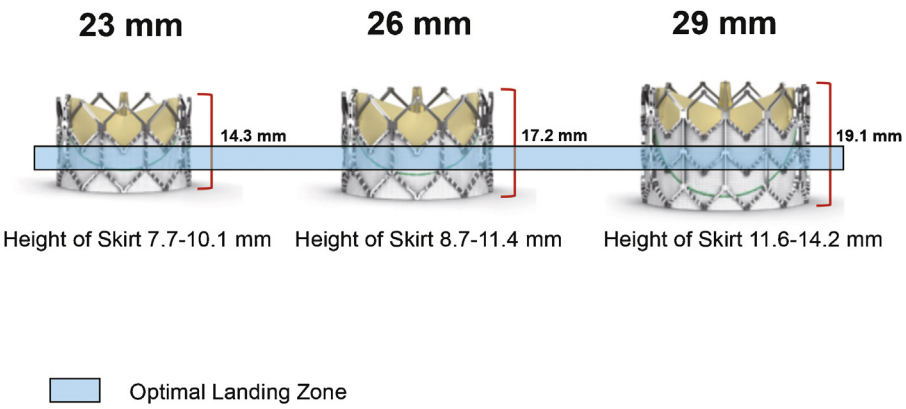

Fig. 5. Skirt height and optimal landing zone for Edwards transcatheter valve 23, 26, and 29 mm, respectively.

Post dilatation

Optimal annulus sizing, and valve positioning, as well as post dilatation when necessary, are instrumental in achieving device implantation success. Post dilatation is the first option for the treatment of significant paravalvular leak after TAVI when the valve is implanted in the appropriate zone. After Edwards valve deployment, post dilatation with the same balloon which was used for deployment with an additional 1–3 cc of contrast media has been shown to be effective in reducing the grade of paravalvular leak [19]. However, excessive balloon oversizing may lead to annulus rupture.

Conclusions

TAVI has already become a mature technique which is integrated into AS clinical paradigms. The heart team approach is crucial for pre-procedural screening and management of pre- and post-procedural complications. Good screening contributes to at least 50% of the final result.

Conflict of interest statement

T. Lefèvre is proctor for transfemoral-TAVI for Edwards Lifesciences, and is consultant for Symetis and Direct Flow Medical.

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